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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,911	03/16/2004	Harada Yosuke	Q-80506	9558
23373	7590	04/02/2007	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			YU, MISOOK	
ART UNIT		PAPER NUMBER		
1642				
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/02/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/800,911	YOSUKE ET AL.
	Examiner MISOOK YU, Ph.D.	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 12 February 2007.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 10 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: Exhibit A (total 3 pages)

## DETAILED ACTION

Claim 10 is pending and under consideration.

### ***Claim Rejections - 35 USC § 112***

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

Applicant argues that the amended claim satisfies written description requirement. The amended claim and applicant argument has been fully considered but this rejection is maintained because the amended claim is drawn to genus of nucleic

acid molecules. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in a form of being capable of hybridizing to the recited sequence. There is not even identification of function associated with the hybridizing molecules. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

***Claim Rejections - 35 USC § 102, Withdrawn***

The rejection of claim 10 under 35 U.S.C. 102(e) as being anticipated by US PAT, 5,932,445 (hereinafter the '445 patent filing date Nov. 7, 1997) is withdrawn because the amended claim is no longer anticipated by the '445 patent.

***Double Patenting, Withdrawn***

The rejection of claim 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,822,083 is withdrawn in view of the Terminal Disclaimer.

***The Following Is New Ground of Rejection***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. 6,107,462 (the '462 patent hereinafter, filing date of 16-Aug-1996).

Claim 10 is drawn to nucleic acid hybridizes to nucleotide 1581 to 2382 of SEQ ID NO: 2 under the recited condition. The '462 patent teaches nucleic acid sequence with 97.1% similarity to nucleotides 1906 to 2382 of the instant SEQ ID NO: 2. Since the sequence disclosed in the '462 patent has 97.1% similarity over 476 nucleotides, it would hybridizes to the recited condition. Note attached sequence alignment (Exhibit A).

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3-28-07

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MISOOK YU, Ph.D.  
Primary Examiner  
Art Unit 1642

<!--StartFragment--> Title: US-10-800-911-2\_COPY\_1581\_2382 Exhibit A  
 Perfect score: 802  
 Sequence: 1 gatgcatgccagtggcaccg.....cagagcagcagccaccacag 802  
 Scoring table: IDENTITY\_NUC  
 Gapop 10.0 , Gapext 1.0  
 Searched: 1403666 seqs, 935554401 residues  
 Total number of hits satisfying chosen parameters: 2807332  
 Minimum DB seq length: 0  
 Maximum DB seq length: 2000000000  
 Post-processing: Minimum Match 0%  
 Maximum Match 100%  
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 9: /EMC\_Celerra\_SIDS3/ptodata/2/ina/RE\_COMB.seq:/\*  
 10: /EMC\_Celerra\_SIDS3/ptodata/2/ina/backfiles1.seq:/\*  
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1581  
 + 325  
—————  
 # 1906  
 416  
—————  
 2382

<!--StartFragment-->RESULT 4  
US-08-699-103B-6  
; Sequence 6, Application US/08699103B  
; Patent No. 6107462  
; GENERAL INFORMATION:  
; APPLICANT: Rine, Jasper D.  
; APPLICANT: Hampton, Randolph  
; TITLE OF INVENTION: GENES AND PROTEINS CONTROLLING  
; TITLE OF INVENTION: CHOLESTEROL SYNTHESIS  
; NUMBER OF SEQUENCES: 25  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: Fish & Richardson P.C.  
; STREET: 2200 Sand Hill Road, Suite 100  
; CITY: Menlo Park  
; STATE: CA  
; COUNTRY: USA  
; ZIP: 94025  
; COMPUTER READABLE FORM:  
; MEDIUM TYPE: Diskette  
; COMPUTER: IBM Compatible  
; OPERATING SYSTEM: DOS  
; SOFTWARE: FastSEQ for Windows Version 2.0  
; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/699,103B  
; FILING DATE: 16-AUG-1996  
; PRIOR APPLICATION DATA:  
; APPLICATION NUMBER: 60/002,581  
; FILING DATE: 17-AUG-1995  
; ATTORNEY/AGENT INFORMATION:  
; NAME: Green, Grant D.  
; REGISTRATION NUMBER: 31,259  
; REFERENCE/DOCKET NUMBER: 09272/005001  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: 650/322-5070  
; TELEFAX: 650/854-0875  
; INFORMATION FOR SEQ ID NO: 6:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 571 base pairs  
; TYPE: nucleic acid  
; STRANDEDNESS: single  
; TOPOLOGY: linear  
; MOLECULE TYPE: Genomic DNA  
US-08-699-103B-6

Query Match 52.9%; Score 424.6; DB 3; Length 571;  
Best Local Similarity 97.1%; Pred. No. 2.3e-133;  
Matches 465; Conservative 0; Mismatches 9; Indels 5; Gaps 3;

Qy 190 6326 TACCATTTCTATGGGTTGG-CACCGATGTAGATTATGAAACTGCATTATTACCG 384  
| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||  
Db 2 TTCCATTCTATGGGTTGGACACCGATGTAGATTATGAAACTGCATTATTACCG 61

Qy 385 TCTGGCTCTGAGCAGCAACACAGTCAGCACAAGCTATGTTAATCTGGATATGCATGA 444  
| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||  
Db 62 TCTGGCTCTGAGCAGCAACACAGTCAGCACAAGCTATGTTAATCTGGATATGCATGA 121

Qy 445 GAAAGGACTGGGCATTAAACAGGATATTCACCTTGCACAGCTTATGACATGGCAGC 504  
| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||  
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Qy 564 TCTATTTCTTGCAGTACATACGGAAACAAACATTGAGATATGTTCACCCAACTTGATA 623  
Db 242 TCTATTTCTTGCAGTACATACGGAAACAAACATTGAGATATGTTCTCCAACTTGATA 301  
Qy 624 TGGACCAGCTTTGGGACCTGAGTGGACCTTACCTCATGACCATCATTGCGCTGCTGT 683  
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&lt;!--EndFragment--&gt;